

We Claim:

1. A pharmaceutical preparation comprising:

- (a) an active substance comprising a tiotropium salt, in a concentration based on tiotropium of between 0.0005 and 5% by weight;
- (b) a solvent selected from water or a water/ethanol mixture;
- (c) acid for achieving a pH between 2.0 and 4.5; and
- (d) a pharmacologically acceptable preservative,

optionally including a pharmacologically acceptable complexing agent, stabilizer, a pharmacologically acceptable cosolvent, or other pharmacologically acceptable adjuvants and additives.

2. The pharmaceutical preparation according to claim 1, wherein the tiotropium salt is a salt formed with HBr, HCl, HI, monomethylsulfuric acid ester, methanesulfonic acid, or *p*-toluenesulfonic acid.

3. The pharmaceutical preparation according to claim 1, wherein the active substance is tiotropium bromide.

4. The pharmaceutical preparation according to claim 1, wherein the active substance is tiotropium bromide monohydrate.

5. The pharmaceutical preparation according to claim 1, wherein the solvent is water.

6. The pharmaceutical preparation according to claim 2, wherein the solvent is water.

09981937-101701

7. The pharmaceutical preparation according to claim 3, wherein the solvent is water.
8. The pharmaceutical preparation according to claim 4, wherein the solvent is water.
9. The pharmaceutical preparation according to claim 1, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.
10. The pharmaceutical preparation according to claim 2, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.
11. The pharmaceutical preparation according to claim 3, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.
12. The pharmaceutical preparation according to claim 4, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.
13. The pharmaceutical preparation according to claim 9, wherein the solvent is a water-ethanol mixture with up to 60 vol.% of ethanol.
14. The pharmaceutical preparation according to claim 13, wherein the solvent is a water-ethanol mixture with up to 30 vol.% of ethanol.
15. The pharmaceutical preparation according to one of claims 1 to 4, wherein the pharmaceutical preparation does not contain a complexing agent.
16. The pharmaceutical preparation according to one of claims 1 to 4, wherein the pharmaceutical preparation does not contain a stabilizer.
17. The pharmaceutical preparation according to one of claims 1 to 4, wherein edetic acid salt is present in an amount of greater than 0 up to 25 mg/100 ml.

18. The pharmaceutical preparation according to claim 17, wherein edetic acid salt is present in an amount of from 5 to less than 10 mg/100 ml.
19. The pharmaceutical preparation according to claim 17, wherein the edetic acid salt is sodium edetate.
20. The pharmaceutical preparation according to one of claims 1 to 4, wherein the pH is between 2.5 and 3.5.
21. The pharmaceutical preparation according to claim 20, wherein the pH is between 2.7 and 3.3.
22. The pharmaceutical preparation according to claim 21, wherein the pH is between 2.7 and 3.0.
23. The pharmaceutical preparation according to one of claims 1 to 4, wherein the concentration based on tiotropium is between 0.001% and 3% by weight.
24. The pharmaceutical preparation according to claim 23, wherein the concentration based on tiotropium is between 0.0005% to 0.5% by weight.
Same as claim 1
25. The pharmaceutical preparation according to claim 24, wherein the concentration based on tiotropium is between 0.0005% to 0.25% by weight.
26. The pharmaceutical preparation according to claim 25, wherein the concentration based on tiotropium is between 0.001% to 0.1% by weight.
27. The pharmaceutical preparation according to one of claims 1 to 4, wherein the pharmacologically acceptable preservative is benzalkonium chloride.

28. The pharmaceutical preparation according to one of claims 1 to 4, wherein the pharmaceutical preparation comprises a pharmacologically acceptable adjuvant or additive.

29. The pharmaceutical preparation according to claim 28, wherein pharmacologically acceptable adjuvant or additive is an antioxidant.

30. The pharmaceutical preparation according to one of claims 1 to 4, wherein the pharmaceutical preparation contains no cosolvents and/or pharmacologically acceptable adjuvants and additives apart from the preservative.

31. A pharmaceutical preparation comprising water, 0.1% by weight of tiotropium bromide, 0.01% by weight of benzalkonium chloride, and 0.05% by weight of sodium edetate, which is adjusted to a pH of 3.0 using hydrochloric acid.

32. A pharmaceutical preparation consisting of:

- (a) an active substance comprising a tiotropium salt, in a concentration based on tiotropium of between 0.0005 and 5% by weight;
- (b) a solvent selected from water or a water/ethanol mixture;
- (c) acid for achieving a pH between 2.0 and 4.5; and
- (d) a pharmacologically acceptable preservative,

optionally including a pharmacologically acceptable complexing agent, stabilizer, a pharmacologically acceptable cosolvent, or other pharmacologically acceptable adjuvants and additives.

33. The pharmaceutical preparation according to claim 32, wherein the tiotropium salt is a salt formed with HBr, HCl, HI, monomethylsulfuric acid ester, methanesulfonic acid, or *p*-toluenesulfonic acid.

34. The pharmaceutical preparation according to claim 32, wherein the active substance is tiotropium bromide.

35. The pharmaceutical preparation according to claim 32, wherein the active substance is tiotropium bromide monohydrate.

36. The pharmaceutical preparation according to claim 32, wherein the solvent is water.

37. The pharmaceutical preparation according to claim 32, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

38. A method for administering a pharmaceutical preparation according to one of claims 1 to 4 or 31 to 37, comprising nebulizing the pharmaceutical preparation in an inhaler selected from the group consisting of: (a) an inhaler according to WO 91/14468, or (b) an inhaler according to Figures 6a and 6b of WO 97/12687.

39. A method for administering a pharmaceutical preparation according to one of claims 1 to 4 or 31 to 37, comprising nebulizing the pharmaceutical preparation in an inhaler which nebulizes defined amounts of the pharmaceutical preparation by the application of pressures from 100 to 600 bar through a nozzle having at least one nozzle opening with a depth of 2 to 10 microns and a width of 5 to 15 microns to form an inhalable aerosol.

40. The method according to claim 39, wherein at least one nozzle opening is at least two nozzle openings which are inclined relative to one another in the direction of the nozzle opening at an angle of from 20 degrees to 160 degrees.

41. The method according to claim 39, wherein the defined amounts of the pharmaceutical preparation are 10 to 50 microliters.

42. The method according to claim 38, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

43. The method according to claim 39, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

44. The method according to claim 38, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

45. The method according to claim 39, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

46. The method according to claim 38, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

47. The method according to claim 39, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

48. The method according to claim 38, wherein the mass of pharmaceutical formulation delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

49. The method according to claim 39, wherein the mass of pharmaceutical formulation delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

50. A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation according to one of claims 1 to 14.

51. A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation using the method of claim 38.

52. A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation using the method of claim 39.

0998193 "10101
T04T0T" 4E6T8660